

### **REMARKS WITH RESPECT TO THE AMENDMENTS**

In order to allow proper examination of the claims, and proper understanding of applicants' response to the restriction requirement, applicants have made a variety of amendments to the claims prior to electing a group and species. In particular, claims 1-22, 24-29, and 31-35 have been amended as follows:

1. Claims 14-25, and withdrawn claims 32-35 have been amended to change Y to Q because Y had been used for two different types of moieties prior to the amendment.
2. Claim 13 has been amended to add a period at the end of the claim
3. Claims 14 and 17 have been amended to read “R<sup>1</sup> is the biologically active compound, as only one biologically active agent is attached to a linking moiety.
4. Claims 15, 16, 18, 19, 21, 22, 24, and 25 have been amended to add –O-C(O)- and –NH-C(O)- as members of the group from which X and Y are selected. Support for this amendment can be found at page 12, lines 11-14 in the specification, which states “Non-limiting examples of the X and Y linkages are (in either orientation): -C(O)O-, -C(O)NH-, -OC(O)NH-, -S-S-, -C(S)O-, -C(S)NH-, -NHC(O)NH-, -SO<sub>2</sub>NH-, -SONH-, phosphate, phosphonate and phosphinate.”
5. Claims 17, 20, 33, and 34 have been amended to add –CONH<sub>2</sub> to the group from which R<sup>5</sup> is selected. Support for this amendment can be found at page 14, lines 7-10 in the specification, which states “In another group of preferred embodiments, the conjugate is represented by formula 2, in which . . . R<sup>5</sup> is CONH<sub>2</sub>. . . .”
6. Claims 26, 27, 28, and 29 have been amended to delete –C(O)O- and replace it with -OC(O)-. Support for this amendment can be found at page 12, lines 11-14 in the specification, which states “Non-limiting examples of the X and Y linkages are (in either orientation): -C(O)O-, -C(O)NH-, -OC(O)NH-, -S-S-, -C(S)O-, -C(S)NH-, -NHC(O)NH-, -SO<sub>2</sub>NH-, -SONH-, phosphate, phosphonate and phosphinate.

7. Claims 26, 27, 28, and 29 have been amended to change dependencies from 12, 13, 14, and 15, to 16, 19, 22, and 25, respectively. Support can be found within the base claims 16, 19, 22, and 25 for the dependency of claims 26-29, whereas support for 26-29 as dependent on claims 13-16 is not present in the claims.
  
8. Claims 32, 33, 34, and 35 have been amended to change dependencies from 20, 21, 21, and 21, to 30, 31, 31, and 31, respectively. The examiner has noted this error in the restriction requirement, and was correct in assuming that the proper dependency is now shown in the amendments.

## **RESPONSE TO RESTRICTION REQUIREMENT**

### **A. Restriction of Claims to Groups I-V**

The examiner has required restriction between five groups of claims:

- (I) claims 3 and 10, drawn to composition of transport moiety with structure (XYZ)<sub>n</sub>Z;
- (II) claims 4 and 11, drawn to composition of transport moiety with structure (ZY)<sub>n</sub>Z;
- (III) claims 5, 12, and 26, drawn to composition of transport moiety with structure (ZYY)<sub>n</sub>Z;
- (IV) claims 6, 13, and 27, drawn to composition of transport moiety with structure (ZZY)<sub>n</sub>Z;
- (V) claims 30-35, drawn to method of use.

Applicants respond to this restriction with traverse. Applicants note that the examiner has stated that inventions I - IV and V are related as process of making and process of using, under MPEP §806.05(f). Applicants respectfully point out that this is inaccurate. Claims in groups I - IV are product claims, while the claims in group V are method of use claims. The appropriate section of the MPEP that applies here is §806.05(h), Product and Process of Using. Applicants assert that the compositions of the claimed invention cannot be used in a materially different process, and that the process of using the claimed compositions cannot be practiced with another, materially different product. Therefore, applicants request that the restriction of group V, claims 30-35, be removed and that the method of use claims be combined with the set of linking claims.

Applicants also note that the dependency of a number of claims has been amended, as shown in the Listing of Claims beginning on page 2 of this Response. In particular, claim 26 is now dependent from claim 16, a linking claim, and claim 27 is now dependent from claim 19, a linking claim, whereas prior to the amendment, claim 26 was dependent from claim 12, and member of Group III, and claim 27 was dependent from claim 13, a member of Group IV. These two claims are therefore linking claims, and should not be subject to restriction into Groups III and IV respectively. Applicants have taken the liberty of adjusting the list of linking claims to

include claims 16 and 17, so that the list is claims 1, 2, 7-9, and 14-29 (and method claims 30-35).

Applicants elect Group II, claims 4 and 11 (in addition to the linking claims 1, 2, 7-9, and 14-29, and method claims 30-35). Applicants expressly reserve their right under 35 USC §121 to file a divisional application directed to the nonelected subject matter during the pendency of this application.

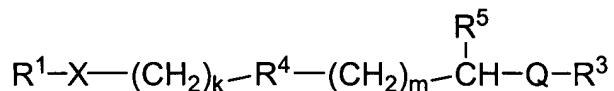
In the event that the examiner does not remove the restriction of claims 30-35, applicants reserve the right to request their rejoinder under 37 CFR §1.104 in the event that at least one of claims 4 and 11 is found allowable.

#### B. Election of Species

The examiner has additionally required the election of a species of transport moiety and a single conjugate structure, clearly identifying all R groups to represent a single variation, X and Y clearly identified and various subscripts such as k, n and m defined to represent an integer.

The elected transport moiety species is the structure  $(R\ aca)_6R$  wherein R is arginine, aca is  $\epsilon$ -amino caproic acid, and n is 6.

The elected conjugate species is the structure



wherein X is  $-OC(O)-$ , Q is  $-NHC(O)-$ , k is 1, m is 1,  $R^4$  is S, and  $R^5$  is  $-C(O)NH_2$ .

Applicants remind the Examiner that because this is a species election, it is for the sole purpose of the Examiner's initial search and examination, and upon allowance of a generic claim, applicants are entitled to have all non-elected species encompassed by that claim examined (37 C.F.R. 1.141).

Application No. 10/078,247  
Response dated December 13, 2005  
Response to Restriction Requirement dated October 14, 2005

Atty Dkt No. 8400-0013  
Client No. S02-222

If the examiner has any questions concerning this communication, or would like to discuss the application, the art, or other pertinent matters, he is welcome to contact the undersigned attorney at (650) 251-7700.

Respectfully submitted,

By: Carol A. Schneider  
Carol A. Schneider, Ph.D., J.D.  
Registration No. 34,923

Reed Intellectual Property Law Group  
1400 Page Mill Road  
Palo Alto, California 94304-1124  
(650) 251-7700 Telephone  
(650) 251-7739 Facsimile